DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FEB 15 2011

Re: ATRYN
Docket No.: FDA-2009-E-0241

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the application for patent term extension for U.S. Patent No. 6,441,145, filed by GTC Biotherapeutics, Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for ATRYN (antithrombin (recombinant)), the human biological product claimed by the patent.

The total length of the regulatory review period for ATRYN is 4,468 days. Of this time, 4,285 days occurred during the testing phase and 183 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this biologic product became effective: November 15, 1996.

   The applicant claims November 14, 1996, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 15, 1996, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: August 8, 2008.

   The applicant claims January 31, 2008, as the date the biologics license application (BLA) for ATRYN (BLA 125284) was initially submitted. However, FDA records indicate that BLA 125284 was submitted on August 8, 2008.

3. The date the application was approved: February 6, 2009.

   FDA has verified the applicant's claim that BLA 125284 was approved on February 6, 2009.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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